

Appl. No. 10/714,575
Atty. Docket No. 0180.00
Office Action dated: 25 September 2006
Reply Dated: 30 May 2007
Customer No. 21968

CLAIMS

In the Claims:

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This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Withdrawn) A composition comprising antibody-containing particles, wherein the particles have a mass median diameter of greater than 7.5 μm and less than 100 μm .
2. (Withdrawn) The composition of claim 1, wherein the particles have a mass median diameter of greater than 10 μm and less than 100 μm .
3. (Withdrawn) The composition of claim 1, wherein the antibody is an antibody fragment.
4. (Withdrawn) The composition of claim 3, wherein the antibody fragment is selected from the group consisting of Fab, F(ab)₂, Fv, and single polypeptide chain binding molecule.
5. (Withdrawn) The composition of claim 1, wherein the antibody is a full-length antibody.
6. (Withdrawn) The composition of claim 1, wherein the antibody is in urine.
7. (Withdrawn) The composition of claim 1, wherein the antibody is dimeric.
8. (Withdrawn) The composition of claim 1, wherein the antibody is CDR-grafted.
9. (Withdrawn) The composition of claim 1, wherein the antibody is humanized.
10. (Withdrawn) The composition of claim 1, wherein the antibody is an antibody-conjugate.

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11. (Withdrawn) The composition of claim 1, wherein the antibody or antibody fragment is a type selected from the group consisting of IgE, IgG, and IgM.
12. (Withdrawn) The composition of claim 11, wherein the antibody is an IgG-type.
13. (Withdrawn) The composition of claim 1, further comprising a pharmaceutically acceptable excipient.
14. (Withdrawn) The composition of claim 13, wherein the pharmaceutically acceptable excipient is present in the antibody-containing particles.
15. (Withdrawn) The composition of claim 13, wherein the pharmaceutically acceptable excipient is comprised of particles separate and distinct from the antibody-containing particles.
16. (Withdrawn) The composition of claim 13, wherein the excipient is selected from the group consisting of amino acid, amino acid derivative, oligopeptide, carbohydrate, inorganic salts, antimicrobial agents, antioxidants, surfactants, buffers, acids, bases, and combinations thereof.
17. (Withdrawn) The composition of claim 16, wherein the excipient is a carbohydrate.
18. (Withdrawn) The composition of claim 17, wherein the carbohydrate is selected from the group consisting of fructose, maltose, galactose, glucose, mannose, sorbose, lactose, sucrose, trehalose, cellobiose, raffinose, melezitose, maltodextrans, dextrans, starches, mannitol, xylitol, lactitol, glucitol, pyranosyl sorbitol, myoinositol, and combinations thereof.
19. (Withdrawn) The composition of claim 17, wherein the carbohydrate is selected from the group consisting of sucrose and trehalose.

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20. (Withdrawn) The composition of claim 16, wherein the excipient is selected from a salt or buffer.

21. (Withdrawn) The composition of claim 20, wherein the salt or buffer is selected from the group consisting of citric acid, sodium phosphate monobasic, sodium phosphate dibasic, and combinations thereof.

22. (Withdrawn) The composition of claim 16, wherein the excipient is a surfactant.

23. (Withdrawn) The composition of claim 22, wherein the surfactant is selected from the group consisting of Tween-20, Tween-80, and combinations thereof.

24. (Withdrawn) The composition of claim 16, wherein the excipient is an amino acid.

25. (Withdrawn) The composition of claim 24, wherein the amino acid is selected from the group consisting of leucine, histidine, and combinations thereof.

26. (Withdrawn) The composition of claim 1, wherein the composition is housed in a syringe.

27. (Withdrawn) The composition of claim 1, wherein the composition is housed in a vial.

28. (Withdrawn) The composition of claim 1, wherein the antibody is noncrystalline.

29. (Withdrawn) The composition of claim 1, wherein the antibody is partially amorphous.

30. (Withdrawn) The composition of claim 1, having substantially no aggregates.

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31. (Currently amended) A reconstituted composition comprising an antibody in an amount of from about 25 mg/mL to about ~~1000~~ 200 mg/mL, a diluent and an optional pharmaceutically acceptable excipient, wherein the reconstituted composition is: (i) formed from adding the diluent to a spray-dried powder comprised of the antibody and the optional excipient, and (ii) is a visually clear reconstituted composition within about 10 minutes of being formed.

32. (Original) The composition of claim 31, in sterile form.

33. (Original) The composition of claim 31, wherein the antibody is an antibody fragment.

34. (Original) The composition of claim 33, wherein the antibody fragment is selected from the group consisting of Fab, F(ab)₂, Fv, and single polypeptide chain binding molecule.

35. (Original) The composition of claim 31, wherein the antibody is a full-length antibody.

36. (Previously presented) The composition of claim 31, wherein the antibody is murine.

37. (Previously presented) The composition of claim 31, wherein the antibody is chimeric.

38. (Previously presented) The composition of claim 31, wherein the antibody is CDR-grafted.

39. (Previously presented) The composition of claim 31, wherein the antibody is humanized.

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40. (Previously presented) The composition of claim 31, wherein the antibody is an antibody-conjugate.

41. (Previously presented) The composition of claim 31, wherein the antibody or antibody fragment is a type selected from the group consisting of IgE, IgG, and IgM.

42. (Original) The composition of claim 41, wherein the antibody is an IgG-type.

43. (Original) The composition of claim 31, wherein the pharmaceutically acceptable excipient is present.

44. (Original) The composition of claim 43, wherein the excipient is selected from the group consisting of amino acid, amino acid derivative, oligopeptide, carbohydrate, inorganic salts, antimicrobial agents, antioxidants, surfactants, buffers, acids, bases, and combinations thereof.

45. (Original) The composition of claim 44, wherein the excipient is a carbohydrate.

46. (Original) The composition of claim 45, wherein the carbohydrate is selected from the group consisting of fructose, maltose, galactose, glucose, mannose, sorbose, lactose, sucrose, trehalose, cellobiose, raffinose, melezitose, maltodextrins, dextrans, starches, mannitol, xylitol, lactitol, glucitol, pyranosyl sorbitol, myoinositol, and combinations thereof.

47. (Original) The composition of claim 45, wherein the carbohydrate is selected from the group consisting of sucrose and trehalose.

48. (Original) The composition of claim 44, wherein the excipient is selected from a salt or buffer.

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49. (Original) The composition of claim 48, wherein the salt or buffer is selected from the group consisting of citric acid, sodium phosphate monobasic, sodium phosphate dibasic, and combinations thereof.

50. (Original) The composition of claim 44, wherein the excipient is a surfactant.

51. (Previously presented) The composition of claim 50, wherein the surfactant is a polysorbate.

52. (Original) The composition of claim 44, wherein the excipient is an amino acid.

53. (Original) The composition of claim 52, wherein the amino acid is selected from the group consisting of leucine, histidine, and combinations thereof.

54. (Original) The composition of claim 31, wherein the composition is housed in a syringe.

55. (Original) The composition of claim 31, wherein the composition is housed in a vial.

56. (Original) The composition of claim 31, wherein the diluent is selected from the group consisting of bacteriostatic water for injection, dextrose 5% in water, phosphate-buffered saline, Ringer's solution, saline, sterile water, deionized water, and combinations thereof.

57. (Original) The composition of claim 31, wherein the optional excipient is present.

58. (Currently amended) The composition of claim 31, wherein the antibody is present in an amount of from about 25 mg/mL to about [[250]] 200 mg/mL.

59. (Original) The composition of claim 31, having substantially no aggregates.

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60. (Withdrawn) A method for preparing a reconstituted composition comprising the steps of providing a spray-dried powder comprised of an antibody and adding a diluent in order to form the reconstituted composition, wherein the antibody is present in the reconstituted composition in an amount of from about 25 mg/mL to about 1000 mg/mL.

61. (Withdrawn) The method of claim 60, wherein the reconstituted composition comprises an excipient.

62. (Withdrawn) The method of claim 61, wherein the excipient is present in the spray-dried powder.

63. (Withdrawn) The method of claim 61, wherein the excipient is added with or after the step of adding the diluent.

64. (Withdrawn) The method of claim 60, wherein the step of providing the spray-dried powder is comprised of combining the antibody in a liquid to form a liquid feed and spray drying the liquid feed to form the spray-dried powder.

65. (Withdrawn) The method of claim 60, wherein the reconstituted composition has substantially no aggregates.

66. (Withdrawn) The method of claim 60, wherein the reconstituted composition becomes visually clear within about 15 minutes of adding the diluent.

67. (Withdrawn) The method of claim 66, wherein the reconstituted composition becomes visually clear within about 10 minutes of adding the diluent.

68. (Withdrawn) The method of claim 67, wherein the reconstituted composition becomes visually clear within about 5 minutes of adding the diluent.

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69. (Withdrawn) The method of claim 60, wherein the diluent is selected from the group consisting of diluent is selected from the group consisting of bacteriostatic water for injection, dextrose 5% in water, phosphate-buffered saline, Ringer's solution, saline, sterile water, deionized water, and combinations thereof.

70. (Withdrawn) The method of claim 60, wherein the antibody is present in the reconstituted composition in an amount of from about 25 mg/mL to about 250 mg/mL.

71. (Withdrawn) A method of administering a composition to a patient comprising administering, via injection, a therapeutically effective amount of an antibody present in a reconstituted composition, wherein the reconstituted composition is comprised of an antibody concentration of from about 25 mg/mL to about 1000 mg/mL, a diluent and an optional excipient, wherein the reconstituted composition is formed from a spray-dried powder comprised of the antibody and the optional excipient.

72. (Withdrawn) The method of claim 71, wherein the injection is a subcutaneous injection.

73. (Withdrawn) The method of claim 71, wherein the injection is an intramuscular injection.

74. (Withdrawn) The method of claim 71, wherein the injection is an intravenous injection.